



Universidad  
de Alcalá



## THE PHARMACY PROFESSION IN THE INDUSTRIAL ENVIRONMENT: CURRICULA DESIGN

Julio Alvarez-Builla G. Depto de Química Orgánica. Universidad de Alcalá

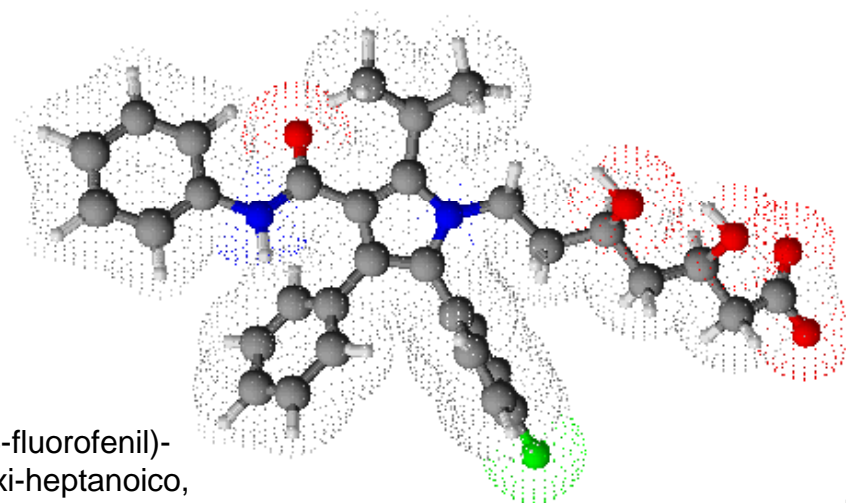
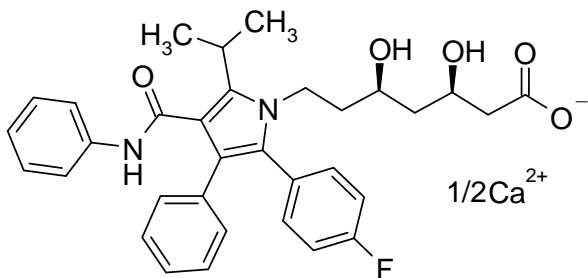


**WHEN A DRUG IS  
DISPENSED**

**WHAT IS INSIDE?**

# The main component

## THE API



www.acdlabs.com

**IUPAC**

Acido 7-[3-fenil-4-fenilcarbamoil-2-(4-fluorofenil)-5-isopropil-pirrol-1-il]-3R,5R-dihidroxi-heptanoico, sal cálcica

**ICN**

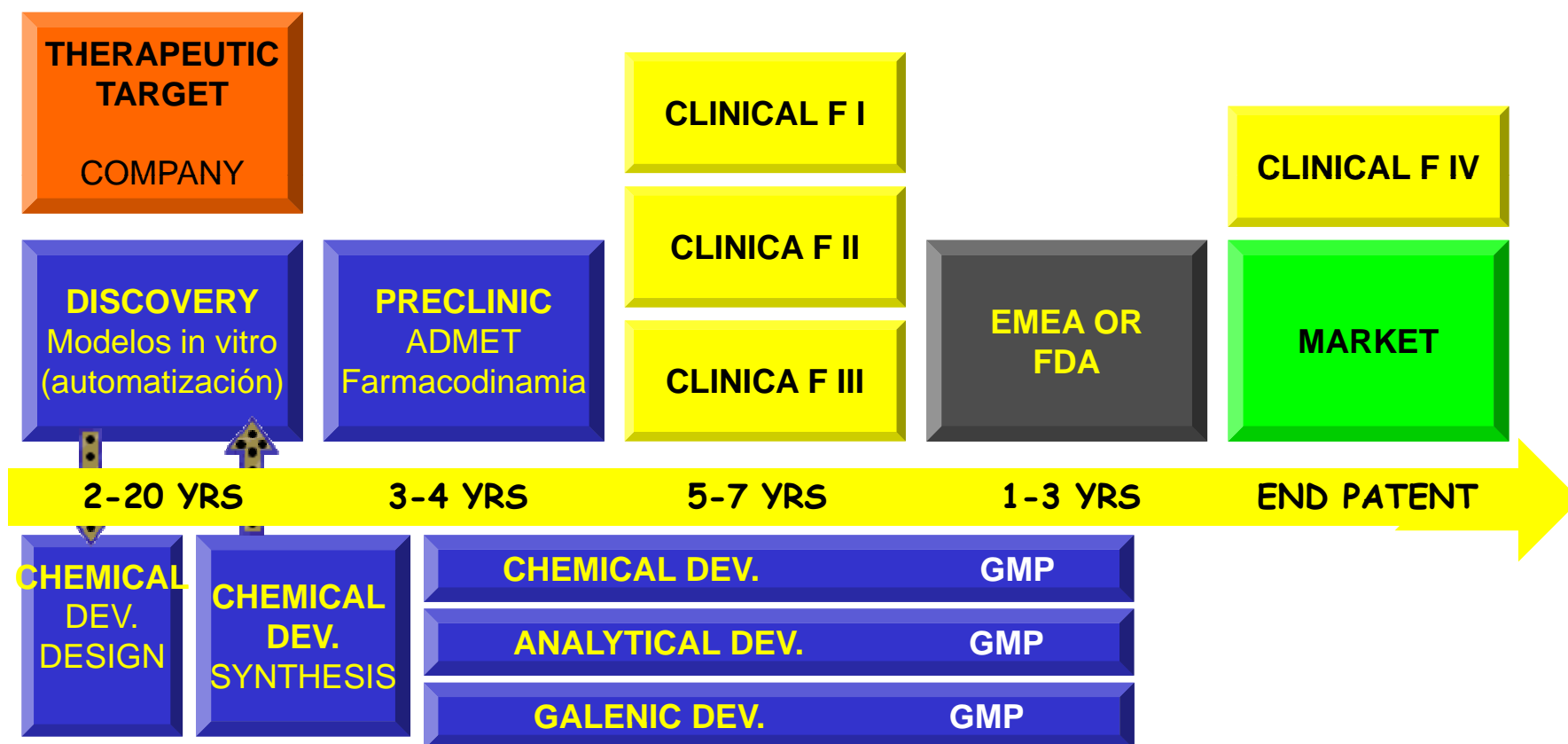
**Atorvastatin**

## THE DRUG

**TRADE MARK** Lipitor, Cardyl, Zarator (PFIZER)  
(hypocolesterolemic)



# DRUG DEVELOPMENT

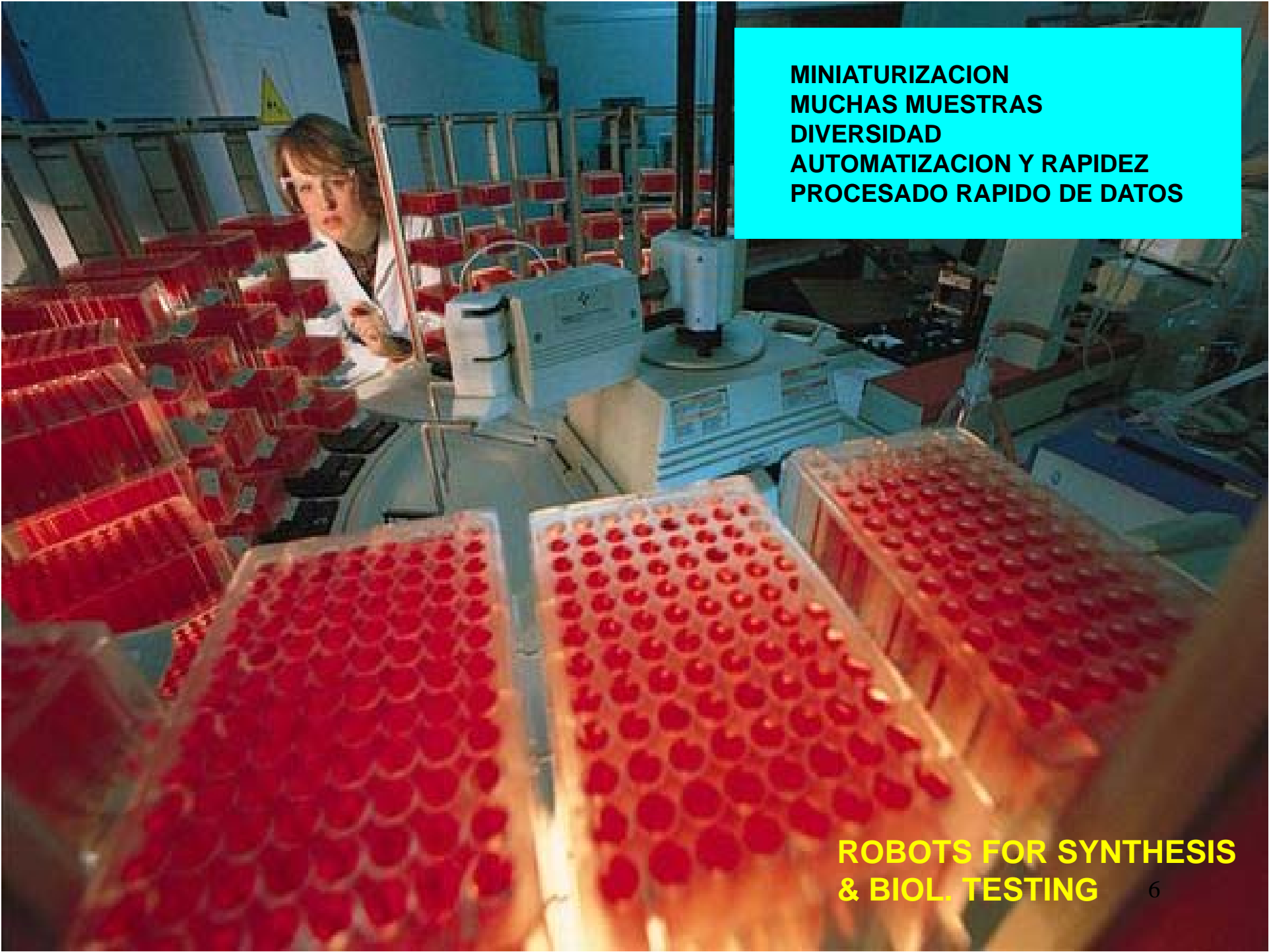


A.M. Cuadro, C. Burgos, J. Alvarez-Builla, *An. Quím.* **2006**, 102 (3), 13-21  
 G. L. Patrick "An Introduction to Medicinal Chemistry" 4th ed. **2009**, 268



# DRUG DEVELOPMENT

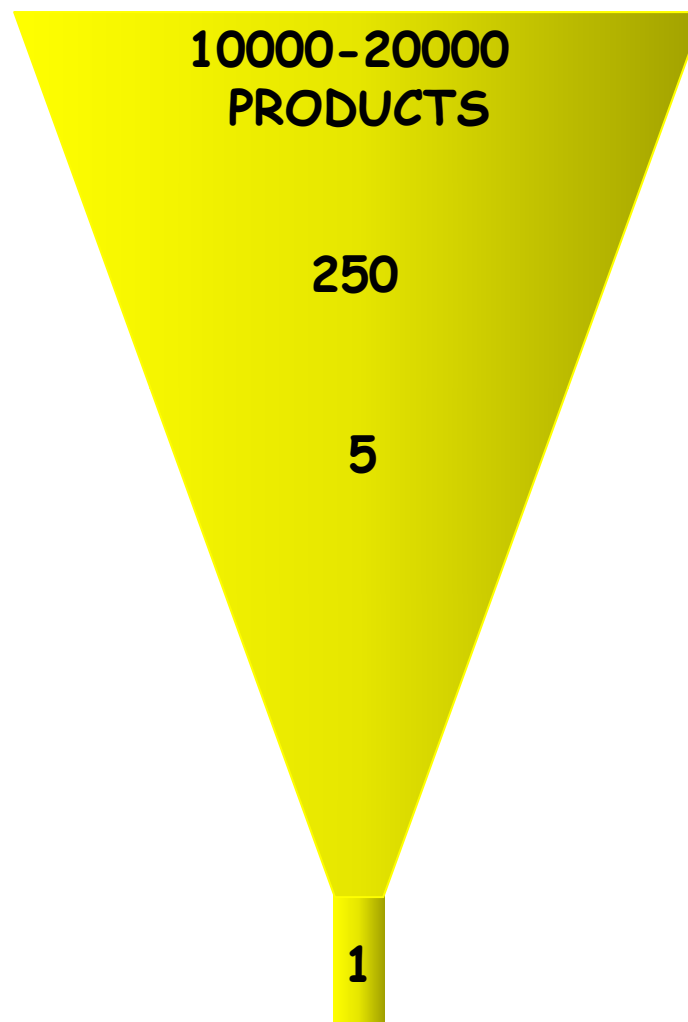
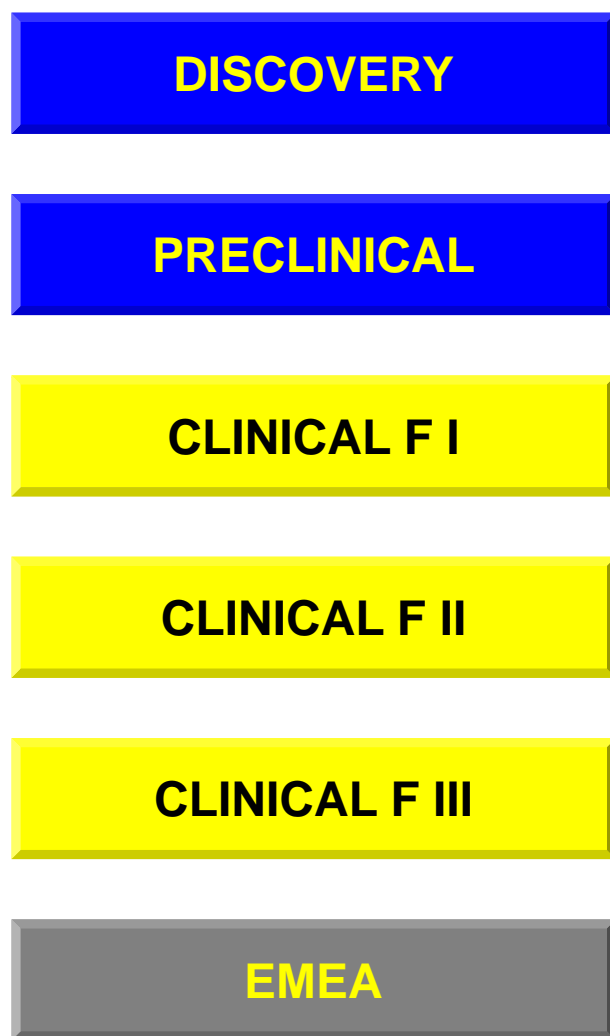


A photograph of a laboratory setting. In the background, a woman with short brown hair, wearing a white lab coat and safety glasses, is looking towards the camera. She is standing behind a workbench. In the foreground, several multi-well plates (microtiter plates) are visible, filled with a red liquid. The plates are arranged in rows, and some are being held by a robotic arm. The laboratory equipment includes a pipette, a microplate reader, and other scientific instruments. The overall scene depicts a high-throughput laboratory environment.

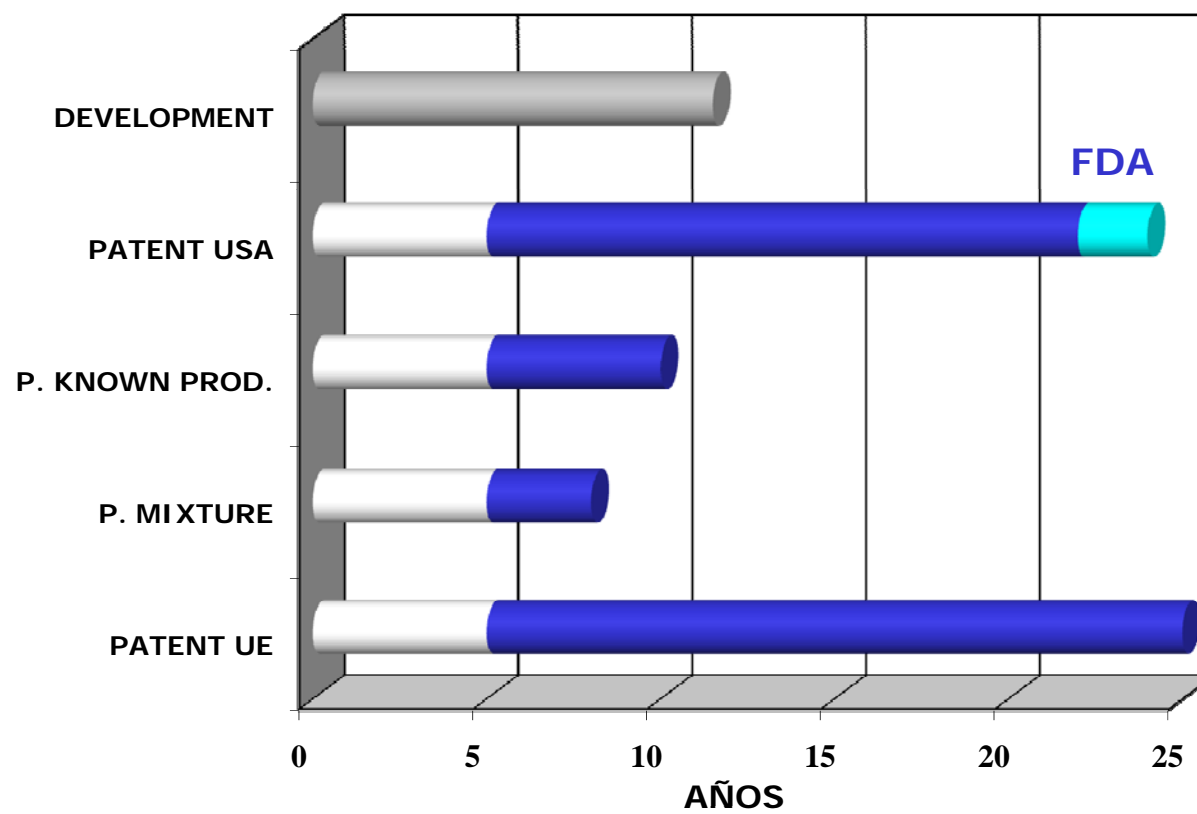
**MINIATURIZACION  
MUCHAS MUESTRAS  
DIVERSIDAD  
AUTOMATIZACION Y RAPIDEZ  
PROCESADO RAPIDO DE DATOS**

**ROBOTS FOR SYNTHESIS  
& BIOL. TESTING**

## DRUG DEVELOPMENT

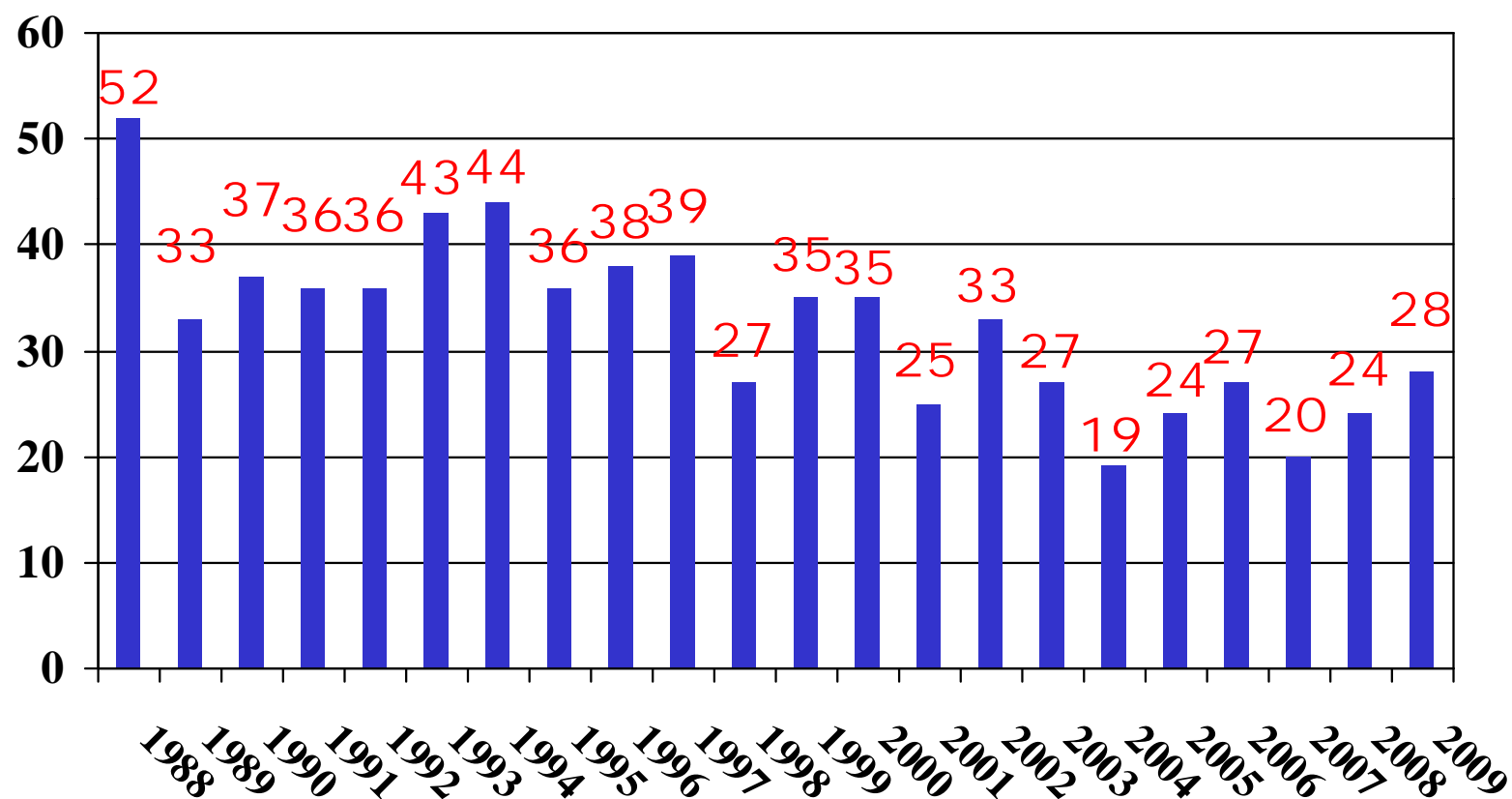


## PATENTS

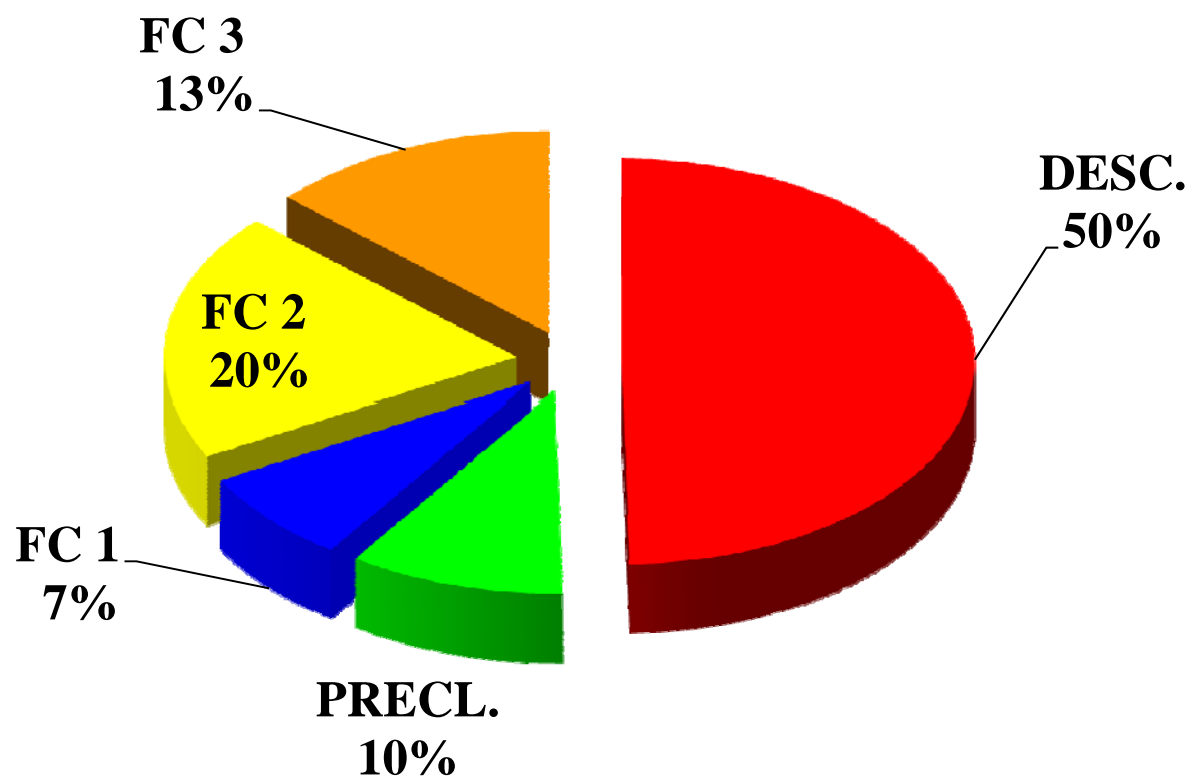




## NCEs y NBEs 1988-2009



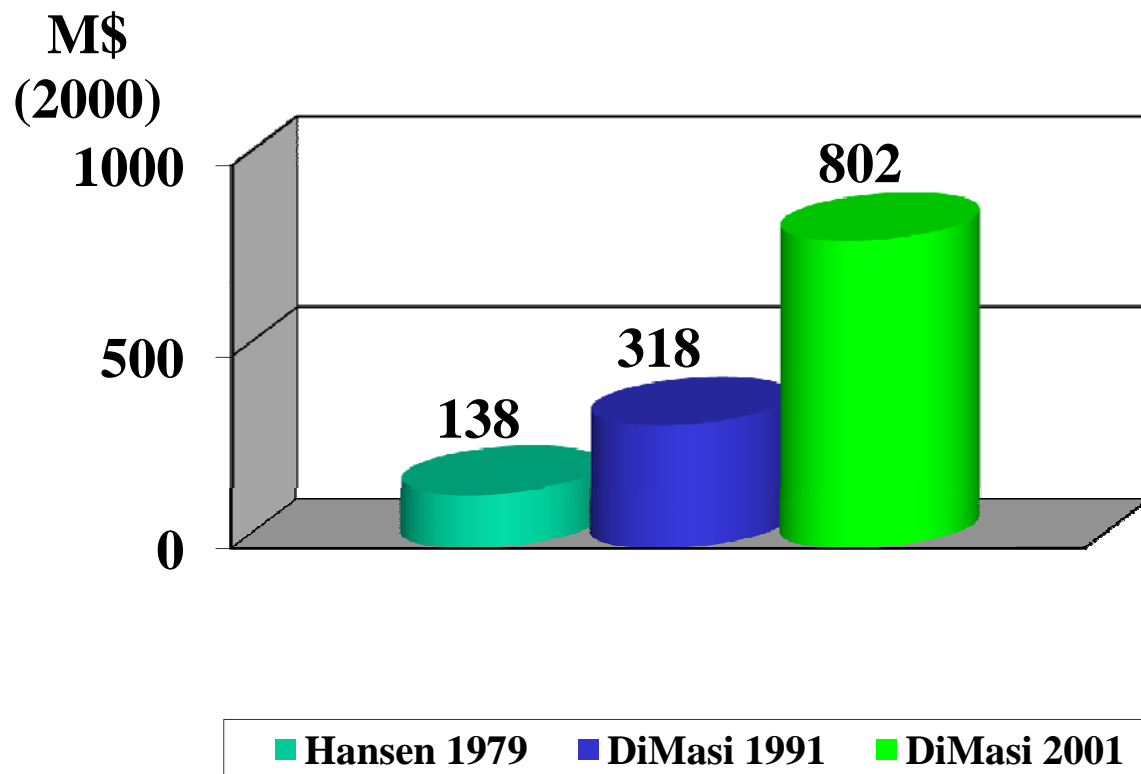
## DRUG DEVELOPMENT COST OF EVERY PHASE



## COST R&D/API



J. A. DiMasi  
Tufts University



**Coste medio, antes de impuestos, del desarrollo de un fármaco (NCE), en el momento de su aprobación**

**COST R&D/API**

**In 2003  
1 NEC 802 M\$-897 M\$  
1 NEC=40 F16**

Ezzel, C., "The price of pills", *Scientific American*, **2003**, July, 25.

**COST R&D/API**

**In 2007  
1 NCE 800 M€  
1 NEC = 3 AIRBUS 380**





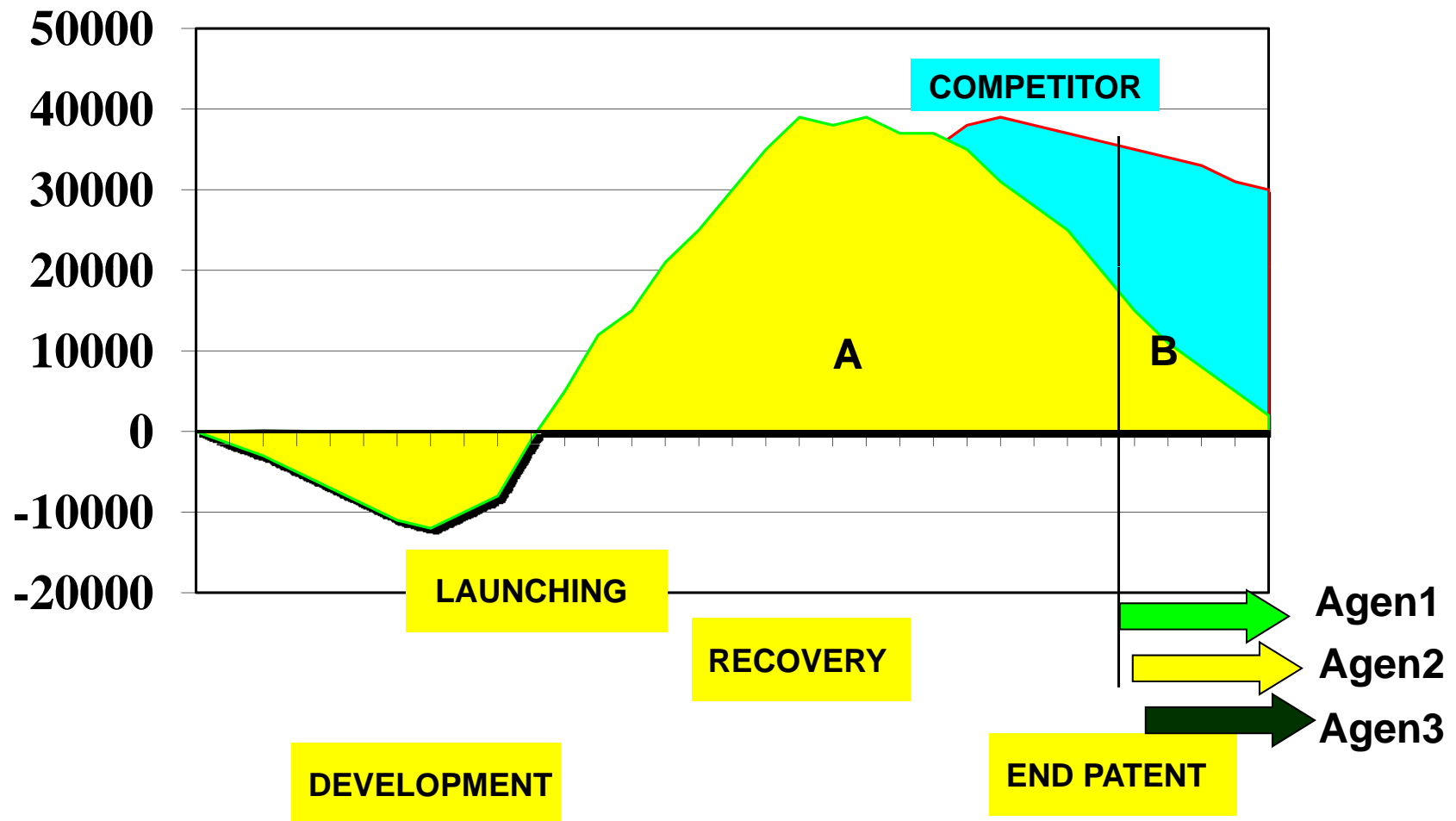
## COST OF A DRUG

c Estimate	Value of item (US\$ millions)
<b>DiMasi estimate in 2000 dollars</b>	802
• Adjustment for post-approval R&D	95
• Adjustment for new indications and non-US approvals (20%)	160
• Adjustment for success rate (11.5% versus 21.5%)	697
<b>Adjusted DiMasi estimate in 2000 dollars</b>	1,754
• Adjustment for inflation (3.7% per year)	592
• Adjustment for other cost increases, such as regulation (8.3% per year)	1,565
<b>Adjusted DiMasi estimate in 2008 dollars</b>	3,911

En 2010  
1 NEC 3911 M\$ = 2749 M€ (2008)  
1 NCE = 7,6 AIRBUS 380  
PrICE Nov 2010



## DRUG LIFE



Nig, R. "Drugs: from discovery to approval" Wiley-Liss 2004, pag 10.

## HOW TO SURVIVE....

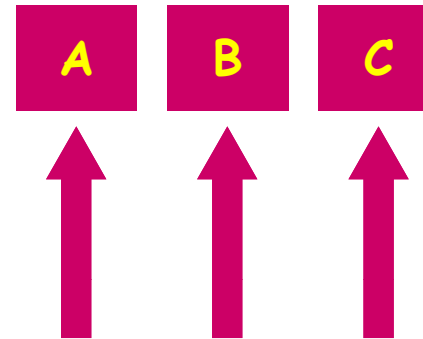
COSTS R+D **GO UP**

COSTS OF PRODUCTION **GO UP.**  
(**QUALITY IS EXPENSIVE**)

BENEFITS LIMITED (**NO ONE WANTS TO PAY**)

**SECTORS OF POPULATION WITHOUT ACCESS TO NEW THERAPIES**

OUTSOURCING



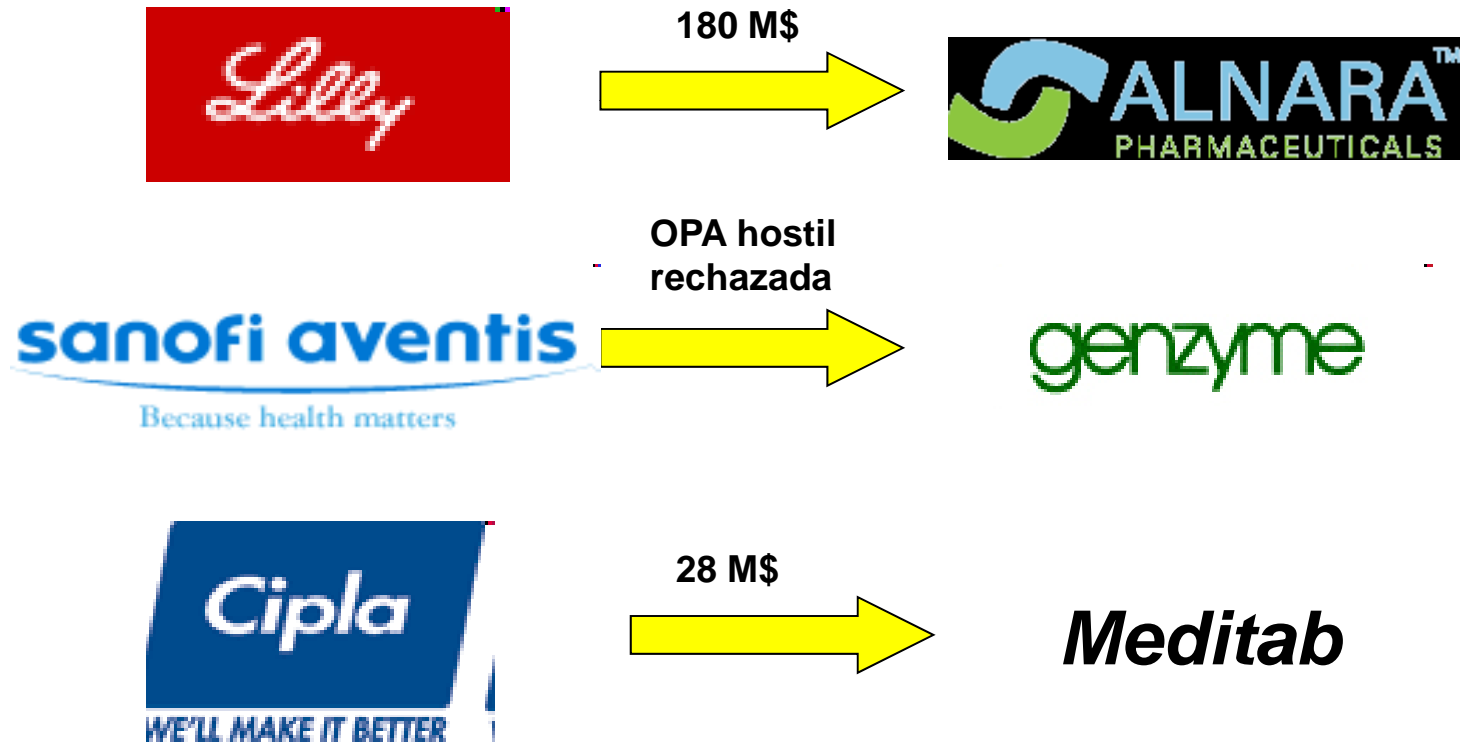
MARKET  
NICHES

COSTS REDUCTION

MERGING  
INTEGRATION

## PHARMA INDUSTRY MEGALABS

### MERGING & ACQUISITIONS IN 2010



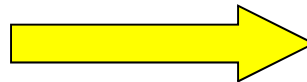


## PHARMA INDUSTRY MEGALABS

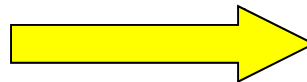
### COMPRAS Y FUSIONES EN 2010



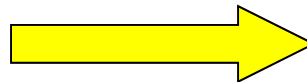
38.700 M\$



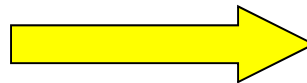
7.100 M\$



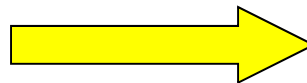
4.000 M\$



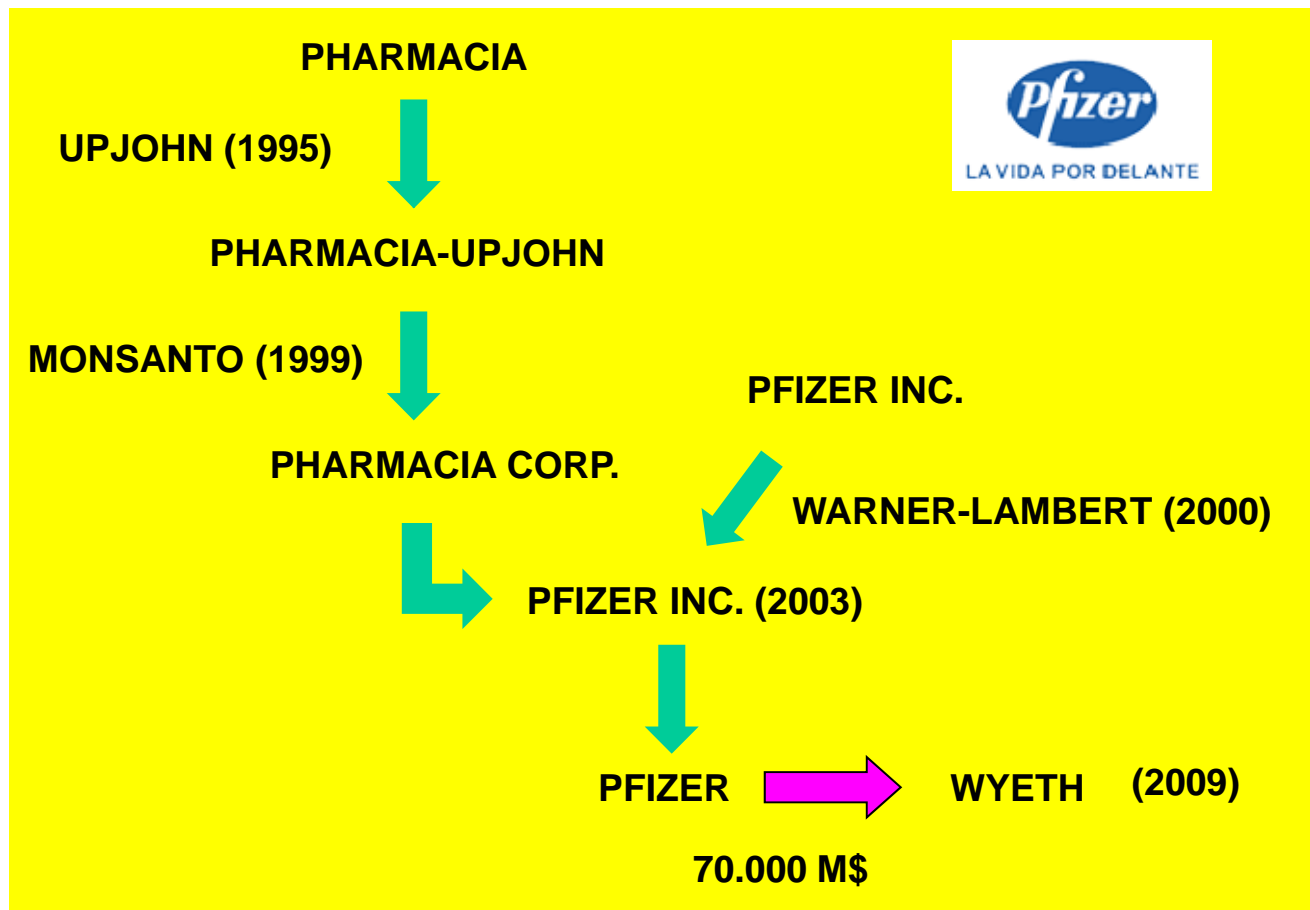
3.300 M\$



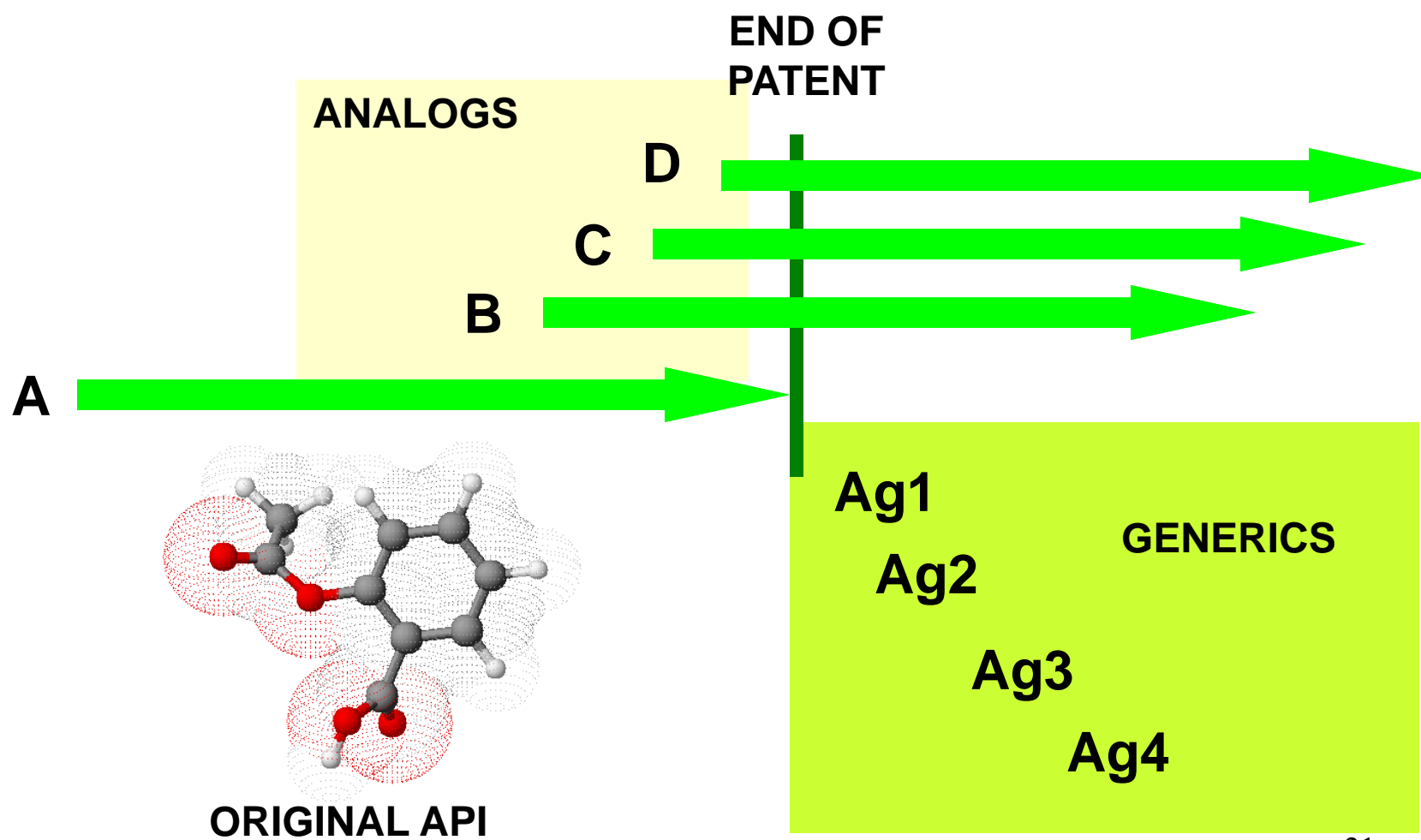
2.900 M\$



## PHARMA INDUSTRY MEGALABS

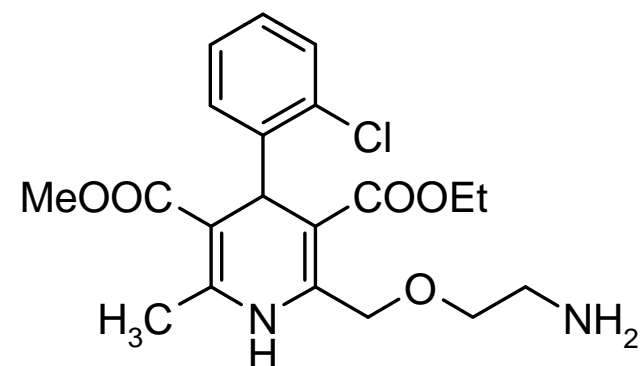


# GENERIC



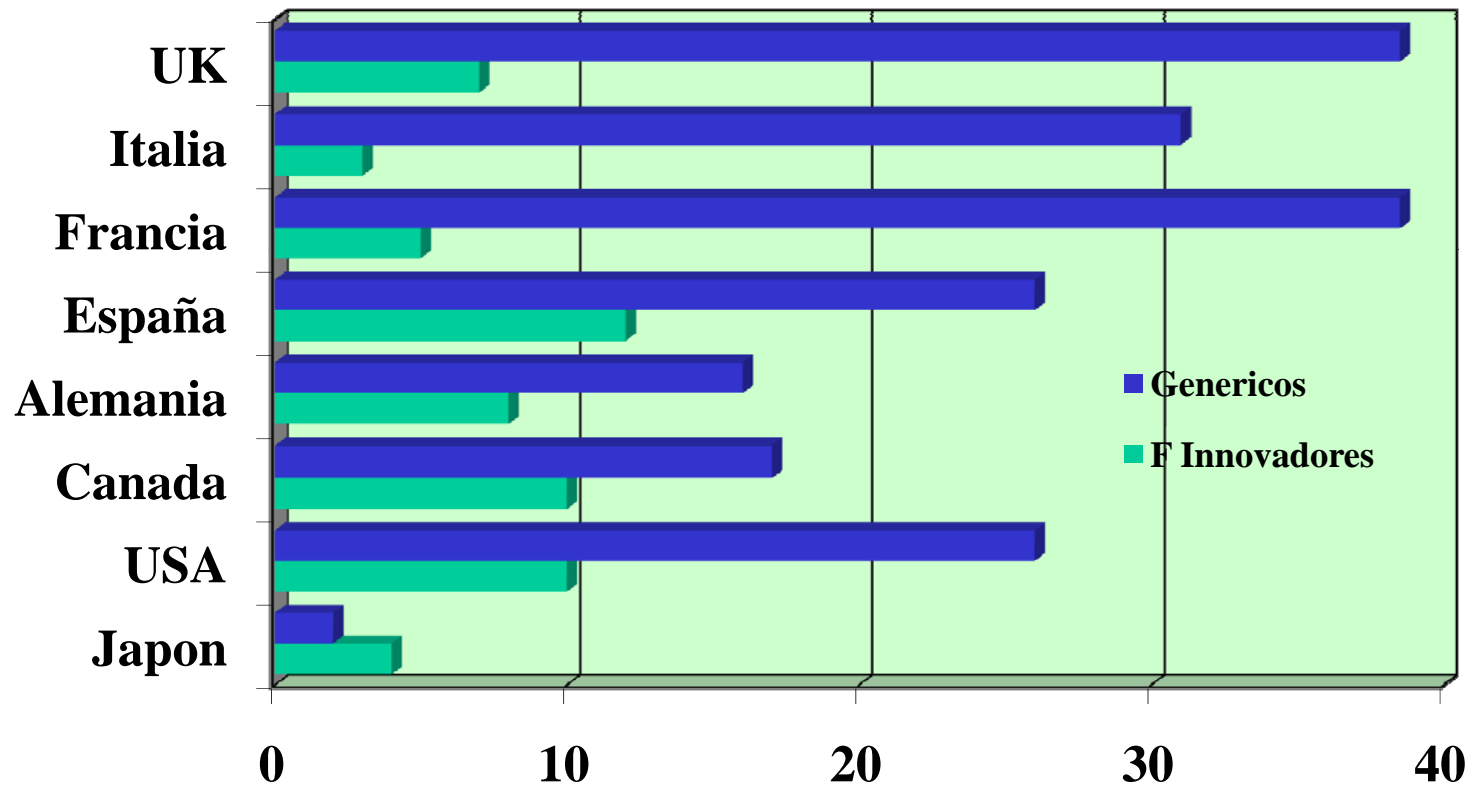
## GENERICIS IN SPAIN

Medicamento	Laboratorio	Dosis	Tamaño	PVP€
<b>2005</b>				
Norvas	Pfizer	10 mg	30 comp	25,00
Amlodipino	Alter	10 mg	30 comp	17,49
Amlodipino	Ratiopharm	10 mg	30 comp	17,49
<b>2008</b>				
Amlodipino	Acebex	10 mg	30 comp	9,83
<b>2010</b>				
Amlodipino	Ratiopharm	10 mg	30 comp	6,50



**Amlodipino**  
Antihipertensivo  
(1983-6 Pfizer)

## % GROWING GENERICS MARKET





## PHARMACY CURRICULUM GRADE IN ALCALA

ASIGNATURAS				
MÓDULO	1 <sup>ST</sup> SEMESTER	2 <sup>ND</sup> SEMESTER	ECTS	Carácter
	FIRST YEAR			
M III	Biología		9	B
M II	Estadística		6	B
M II	Principios de Física y Biofísica		6	B
M I	Química General Inorgánica - Orgánica		9	B
M III		Bioquímica y Biología Molecular I	6	B
M I		Fisicoquímica	6	B
M I		Química Inorgánica	6	O
M VI		Historia de y Metodología Científica	6	O
		Transversal	6	O

## PHARMACY CURRICULUM GRADE IN ALCALA

1ST YEAR				
MÓDULO	1ST SEMESTER	2ND SEMESTER	ECTS	Carácter
	SEGUNDO CURSO			
M III	Bioquímica y Biología Molecular II		9	B
M I	Química Orgánica		9	B
M III		Botánica Farmacéutica y Farmacognosia	9	O
M V		Fisiología Humana	9	O
M I	Microbiología, Parasitología y Virología		12	O
M III	Técnicas Analíticas (Análisis Químico e Instrumental)		12	O

## PHARMACY CURRICULUM GRADE IN ALCALA

	TERCER CURSO			
M IV	<b>Biofarmacia y Farmacocinética</b>		6	○
M IV	<b>Farmacia Galénica I</b>		6	○
M V	<b>Fisiopatología</b>		6	○
M V	<b>Inmunología, Genómica y Farmacogenómica</b>		6	○
M IV		<b>Farmacia Galénica II</b>	6	○
M V		<b>Farmacología y Farmacoterapia I</b>	9	○
M V		<b>Nutrición y Bromatología</b>	9	○
M I	<b>Química Farmacéutica</b>		12	○

## PHARMACY CURRICULUM GRADE IN ALCALA

	CUARTO CURSO			
M IV	<b>Dermofarmacia y Productos Sanitarios</b>		6	O
M IV	<b>Formulación de medicamentos</b>		6	O
M V	<b>Toxicología</b>		6	O
M V		<b>Farmacia Práctica Integrada</b>	6	O
M VI		<b>Gestión, Legislación y Deontología</b>	6	O
M VI		<b>Salud Pública</b>	6	O
M V	<b>Farmacología y Farmacoterapia II</b>		12	O
M V	<b>Métodos Biológicos de Diagnóstico en el Laboratorio de Bioquímica, Microbiología, Parasitología y Hematología</b>		12	O
MATERIAS: B: básica, O: obligatoria, OP: optativa				

## PHARMACY CURRICULUM GRADE IN ALCALA

	QUINTO CURSO			
	Optativa 1	Optativa 1	6	OP
	Optativa 2	Optativa 2	6	OP
	Optativa 3	Optativa 3	6	OP
	Optativa 4	Optativa 4	6	OP
M VII	Prácticas Tuteladas	Prácticas Tuteladas	30	O
M VII	Trabajo Fin de Grado	Trabajo Fin de Grado	6	O
MATERIAS: B: básica, O: obligatoria, OP: optativa				



## PHARMACY CURRICULUM GRADE IN ALCALA

### OPTIONAL TOPICS (4,5 ECTS)

MOLECULAR BASIS OF PHARMACOLOGY  
DRUG SYNTHESIS  
ADVANCED INSTRUMENTAL METHODS  
DRUG ANALYSIS  
QUALITY CONTROL IN PHARMA INDUSTRY  
PHARMACEUTICAL TECHNOLOGY  
DERMOPHARMACY  
DRUG SPECTROSCOPY

### OTHER TOPICS

PROFESIONAL ORIENTATION IN THE PHARMA INDUSTRY  
(AEFI)  
PHARMACEUTICAL PRODUCTION (FROST/ROVI)  
OPERATIONS IN PHARMACEUTICAL PLANT (FROST/ROVI)  
PHARMACEUTICAL MARKETING  
MASTER IN PHARMA INDUSTRYMANAGEMENT (ROCHE)

## CONCLUSIONES

EL MERCADO FARMACEUTICO COMERCIALIZA PRODUCTOS -FARMACOS Y MEDICAMENTOS- QUE AFECTAN A LA SALUD Y LA VIDA DE LOS PACIENTES, ES POR ELLO

## EL MERCADO MAS CONTROLADO DEL MUNDO

- 1) GRANDES MULTINACIONALES (CADA VEZ MAS GRANDES) EXPLOTAN "FARMACOS DE MARCA" INNOVADORES
- 2) EMPRESAS MAS PEQUEÑAS EXPLOTAN FARMACOS GENERICOS MAS CONSERVADORES (EMERGENTES)
- 3) EL DESARROLLO DE UN FARMACO INNOVADOR ES CADA VEZ MAS CARO Y ARRIESGADO,
- 5) LAS REACCIONES ADVERSAS Y EL PRECIO DE LOS NUEVOS FARMACOS, GENERAN MALA IMAGEN DE ESTA INDUSTRIA